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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/613,363	07/03/2003	Milan N. Stojanovic	66710-A/JPW/PJP	7249

7590 07/20/2006

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EXAMINER	
DEJONG, ERIC S	

ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 07/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/613,363	STOJANOVIC, MILAN N.	
	Examiner	Art Unit	
	Eric S. DeJong	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05/05/2006*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED OFFICE ACTION

SEQUENCE COMPLIANCE

The objection to the disclosure for failure to comply with CFR § 1.821(a)(1) and (a)(2) is withdrawn in view of amendments made to the instant specification and the sequence listing filed by application on 05/05/2006.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-18, are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility. This rejection is newly applied.

The disclosure asserts several applications and uses of the instant claimed macromolecular assembly. In summary, the claimed invention is an assembly comprising catalytic nucleic acid leg units which catalyze an nucleic acid "fuel" substrate tethered to a surface. As such, applicants put forth that the assembly has utility in investigating trail movements of the units across a surface and can be utilized to modify traces in order to deposit metallic materials (see page 6, lines 30-37 of the instant specification). Further, applicants disclose envisioning applications of the assembly that include the targeting of movement on bio-mimetic membranes, nano-pattering, tissue

repair, detection of mechanical defects on surfaces, and construction of intelligent sensors and drug delivery tools (see page 10, lines 10-19 of the instant specification). While applicants asserted applications and potential uses of the claimed invention are found to be specific utilities, they are not found, however, to have both a specific and substantial asserted utility as further noted below.

The above cited applications and uses of the claimed assembly rely upon speculated utilities or generic applications that are not drawn from any well known application of the properties of the instantly claimed invention, namely the modification nucleic acids following attachment to a surface by means of a separate ribozyme or other catalytic nucleic acid enzyme. A review of the pertinent art related to surface attached nucleic acids has not revealed any case of modifying a surface bound nucleic acid sequence by means of a separate catalytic nucleic acid, such as any of the ribozymes disclosed in the instant application as a preferred embodiment for arms of the claimed assembly. In contrast, nucleic acids that are typically tethered/linked to a surface are first prepared and modified to a desired specification prior to being attached to a surface. See for example Goldsborough (U.S. Patent N0. 6,794,140), at least column 15, lines 18-39. Therefore, applicants claimed invention drawn to an assembly comprising catalytic leg units that modify tethered nucleic acid "fuel" substrates lacks any substantial utility.

Claims 1-18, 20, and 21 are also rejected under 35 U.S.C. 112, first paragraph. This rejection is newly applied. Specifically, since the claimed invention is not supported

by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Double Patenting

The provisional rejection of claims on the grounds of nonstatutory obviousness-type double patenting as being unpatentable over claims in Application No. 10/189,103 is withdrawn in view of the abandonment of Application No. 10/189,103.

Response to Arguments

Applicant's arguments filed 05/05/2006 have been fully considered but they are not persuasive.

Applicants note that the asserted use is directed to the delivery of the biologically active material rather than the biologically active material itself and, therefore, MPEP § 2107.03 is not germane to assessing the asserted utility.

Regarding the consideration of asserted therapeutic or pharmacological utilities, the MPEP §2107.03 (I) states:

> As a general matter, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility. Cross v. Iizuka, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); Nelson v. Bowler, 626 F.2d 853, 206 USPQ 881 (CCPA 1980). An applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence (e.g., articles in

> scientific journals), or any combination thereof. The applicant does not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty, nor does he or she have to provide actual evidence of success in treating humans where such a utility is asserted. Instead, as the courts have repeatedly held, all that is required is a reasonable correlation between the activity and the asserted use. Nelson v. Bowler, 626 F.2d 853, 857, 206 USPQ 881, 884 (CCPA 1980).

In response to applicants argument, it is noted that the instantly claimed macromolecular assembly is asserted to be useful as a drug delivery tool (see page 10, lines 10-19 of the instant specification), which is a relevant asserted therapeutic use correlating an activity of the claimed assembly with its asserted utility. Since MPEP § 2107.03 sets forth that evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility, applicants argument that MPEP §2107.03 is not germane to assessing the instantly asserted utility of the claimed invention is not found persuasive.

Applicants argue that the asserted use of the claimed macromolecular assembly is for drug delivery, is a real world use for the disclosed invention and provides for a substantial utility. Further, applicants also note that the usefulness of cleaving bound oligonucleotides, and thus the simultaneous release of a portion of a portion of said nucleotide, is immediately apparent to one of skill in the art.

In response to applicants arguments that drug delivery is a substantial utility for the claimed macromolecular assembly, it is reiterated from the above rejection that the asserted utilities of the instantly claimed assembly rely upon speculated utilities or

generic applications that are not drawn from any well known application of the properties of the instantly claimed invention. A review of the pertinent art related to surface attached nucleic acids has not revealed any teaching wherein surface bound nucleic acid sequence have been modified by means of a separate catalytic nucleic acid, in the context of drug delivery. Therefore applicants arguments are not found persuasive.

Applicants further argue that the claimed macromolecular assembly cleaves tethered oligonucleotides thus releasing non-tethered portions into solution, which may be used for the delivery of drugs (which are oligonucleotides) into solution. Upon review of the instant disclosure, there are no teachings that relate the asserted utility of drug delivery to the release of cleaved oligonucleotide portions into solution. It is further noted that the instant claims are not limited to embodiments wherein cleaved portions of the oligonucleotide substrate is a drug, nor do the claims recite any limitation wherein the solution that cleaved oligonucleotide portions are released into contain any targets for drug delivery. Therefore applicants arguments are not found persuasive. Further, applicants response does not contain any references to any teachings in the related arts or teachings from the instant disclosure that might provide evidence in support of the asserted utilities for the claimed invention. As such, there does not appear to be a reasonable correlation between the claimed macromolecular assemblies and the asserted use as a drug delivery tool. Therefore applicants arguments are not found persuasive.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

EDJ EDJ

JOHN S. BRUSCA, PH.D
PRIMARY EXAMINER
13 July 2006